UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ELMER HEISNER, Individually and on Behalf of JAYNE HEISNER,	)	
Plaintiff,	)	**Case No.: 08 C 593**
vs.	)	
	)	**Judge Coar**
GENZYME CORPORATION, a Massachusetts Corporation,	)	**Magistrate Judge Denlow**
Defendant.	)	

Memorandum of Law In Support of Defendant Genzyme's Rule 12 (b)(6) Motion to Dismiss to Complaint

On January 28, 2008, plaintiff Elmer Heisner filed a seven-count complaint against defendant Genzyme Corporation ("Genzyme") seeking damages in connection with the death of his wife, Jayne Heisner. The crux of the complaint is that Genzyme defectively made and marketed a prescription medical device ("Seprafilm®") which was used in surgery on Mrs. Heisner and caused her illness and death. Plaintiff's causes of actions are predicated on various common law torts as well as statutory claims.

The suit, however, should not proceed. Six of the seven counts are preempted under the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetics Act because Seprafilm is a Class III medical device given "premarket approval." 21 U.S.C. § 360k(a). *See also Riegel v. Medtronic*, 128 S. Ct. 999, 1009-11 (2008) (negligence, strict-liability, and implied warranty claims brought against the manufacturer of a Class III device are preempted by the MDA). In addition, every count in the complaint suffers from multiple pleading defects that are also fatal to the claims. For these reasons, even assuming the truth of the allegations in the complaint, the plaintiff has failed to state a claim upon which relief can be granted Fed. R. Civ. P. 12(b)(6). The entire complaint should be dismissed.

ALLEGATIONS AND PUBLIC RECORD FACTS SUPPORTING THE MOTION

A. Key Allegations of the Complaint.

On January 19, 2006, Jayne Heisner, an Illinois resident, underwent surgery to remove an ovarian cyst. (Complaint ("C.") ¶ 2.) To prevent potential post-surgical adhesions, a Seprafilm adhesion barrier was placed into her body. *Id.* Seprafilm is a medical device developed, manufactured, and marketed by Genzyme, a Massachusetts corporation. (C. ¶¶ 3-5.) Seprafilm was approved by the United States Food and Drug Administration ("FDA"). (C. ¶ 12.) The FDA is aware that Seprafilm may cause death or permanent injuries including, among other adverse reactions, severe chronic inflammation of the small bowel area, small bowel obstruction, concrete abdomen, concrete intestines, adhesion of internal organs, dense fibroids, extremely high fever, severe adhesive intestinal obstruction, and vaginal bleeding. (C. ¶ 14.) The Seprafilm adhesion barrier used to treat Jayne Heisner reached plaintiff without substantial change in its condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned, and otherwise distributed. (C. ¶ 32.) Mrs. Heisner developed concrete intestines after Seprafilm was implanted into her body, and died on February 22, 2006. (C. ¶¶ 2, 35.)

B. Seprafilm is a Class III Medical Device Approved Under the Premarket Approval ("PMA") Process.

It is a matter of public record that Seprafilm is regulated by the FDA as a Class III medical device subject to the premarket approval ("PMA") regulatory process. On August 12, 1996, the FDA notified Genzyme that it had granted premarket approval of Seprafilm, as shown in the FDA's publicly available records.[1] The agency's letter states that it issued approval pursuant to Section 515 of the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C.

§360e, the statute governing premarket approval. (*Id.*) Multiple public records show Seprafilm is designated as a Class III/PMA device, including the announcement by the FDA in the Federal Register, 62 Fed. Reg. 18,638 (April 16, 1997)[2] as well as documents available on the agency's official website showing Seprafilm's classification as a "Barrier, Absorable [*sic*], Adhesion" device[3] and that "Barrier, Absorable [*sic*], Adhesion" devices are Class III devices.[4]

C. Plaintiff Seeks Recovery of Damages Under a Variety of Illinois Common Law and Massachusetts Statutory Claims.

Counts I and II plead statutory claims under Massachusetts law for breach of implied warranty of merchantability and deceptive practices. Counts III, IV, V, VI and VII plead common law claims that appear under Illinois law for strict liability, negligence, negligence *per se*, breach of express warranty and breach of implied warranty of merchantability. Depending on the count, the plaintiff seeks compensatory damages, punitive damages and damages for "loss of consortium and society," among other types of relief. Finally, plaintiff seeks damages pursuant to the Illinois Wrongful Death Act as well as an erroneously cited statute that he calls "the State of Illinois Survival Act."

ARGUMENT

I. Standard for Deciding a 12(b)(6) Motion to Dismiss.

Federal Rule of Civil Procedure 12(b)(6) requires dismissal of a complaint when a plaintiff fails to state a claim upon which relief may be granted. *See, e.g., Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1080 (7th Cir. 1997). For purposes of ruling

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[1] *See* PMA Final Decisions Rendered For August 1996, http://www.fda.gov/cdrh/pmaaug96.html (last visited April 8, 2008), which includes the agency's link to the Seprafilm approval letter, P950034.
[2] Federal Register Online, http://frwebgate3.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=7647565375+5+0+0&WAISaction=retrieve (last visited April 8, 2008).
[3] FDA Premarket Approval Database, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/PMA.cfm?ID=7432 (last visited April 8, 2008).
[4] FDA Product Classification Database Search, http:// //www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm (last visited April 8, 2008).

on the motion, the Court must accept as true all well-pleaded facts alleged in the complaint and draw all reasonable inferences from those facts in the plaintiff's favor. *Dixon v. Page,* 291 F.3d 485, 486 (7th Cir. 2002).

In addition, the Court may take judicial notice of matters of public record without converting the motion to one for summary judgment. *Anderson v. Simon,* 217 F.3d 472, 474-75 (7th Cir. 2000); *Henson v. CSC Credit Servs.,* 29 F.3d 280, 284 (7th Cir. 1994) (noting that numerous courts have appropriately considered matters of public record in ruling on a motion to dismiss); *U.S. v. Wood*, 925 F.2d 1580, 1582 (7th Cir. 1991). Under this standard, courts have recognized postings by the FDA in the Federal Register and on the FDA's official website. *See, e.g., Anspach v. City of Philadelphia, Dept. of Pub. Health,* 503 F.3d 256, 273 n.11 (3d Cir. 2007) (taking judicial notice of an announcement by the FDA because it was published in the Federal Register and was "therefore a public record"); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (noting that reports of administrative bodies, including drug approval listings by the FDA, are considered matters of public record and "[t]he fact that an agency report is 'published' on the world wide web does not affect the Court's ability to take judicial notice of the contents of that report").

II. Because Seprafilm is a Class III Medical Device Approved by the FDA Under the PMA Process, Six of the Complaint's Seven Counts Are Preempted.

A. The MDA's Preemption Clause Covers Statutory and Common Law Claims for Strict Liability, Negligence, Implied Warranty and Deceptive Marketing.

The MDA includes an express preemption clause that states:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

> (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

It is now settled law that the MDA preempts any statutory or common law claim that would impose requirements on a manufacturer of a Class III medical device that was approved through the PMA process which are different from or in addition to requirements imposed by the FDA. *Riegel*, 128 S. Ct. at 1011. The design, manufacture, and labeling of a device, which are approved by the FDA as part of the PMA process, are "requirements" as that term is used in the MDA. *Id.* at 1007. As explained in *Riegel*, the PMA process includes an exhaustive FDA review and a determination that the Class III medical device "offers a reasonable assurance of safety and effectiveness." *Id.; see also Medtronic v. Lohr*, 518 U.S. 470, 477 (1996) (detailing the PMA process). In the course of the PMA process, the FDA reviews the device's proposed labeling, makes an express determination that the labeling of a device is neither false nor misleading, and may also impose device-specific restrictions,. *Id*. at 1004-05 (noting that the FDA spends an average of 1,200 hours reviewing each PMA application, that the agency is required to weigh probable benefits against any probable risk of injury or illness from use of the device, and that the agency can "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives") (citing 21 U.S.C. §§ 360e(d)(1)(A) and 360j(e)(1)). Once approval has been granted, a manufacturer may not make any change in design specifications, manufacturing process, labeling, or any other attribute that would affect safety or effectiveness absent express permission from the FDA. *Id.* at 1005 (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

The *Riegel* Court held that because common law causes of action could have the effect of imposing requirements that are different from or in addition to those mandated by the FDA, such

claims are preempted by the MDA. *Id.* at 1008 ("State tort law that requires a manufacturer's [Class III medical device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect."). For these reasons, the *Riegel* Court affirmed the dismissal of the claims for strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing and sale of the challenged device. *Id.* at 1011.

Riegel echoed earlier rulings by a variety of Circuit Courts of Appeal, including our own. In *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), the court ruled that misbranding and mislabeling claims concerning a Class III/PMA device were preempted because "[t]he sufficiency of this information has been approved explicitly by the FDA." Similarly preempted were strict liability, implied warranty, and negligence claims challenging the safety of the *Mitchell* device because they would conflict with the FDA's determination that its requirements rendered the product safe and effective. *Id.* at 913-15.

The MDA also preempts *statutory* claims that would have the effect of imposing requirements different from or in addition to those mandated by the FDA. 21 CFR § 808.1(b) (duties "having the force and effect of law whether established by *statute*, ordinance, regulation, or *court decision* . . . .") (emphasis added). *See also Riegel*, 128 S.Ct. at 1006; *Medtronic, Inc.*, 518 U.S. at 484 (noting that the MDA "expressly preempts state law" and that the language of the preemption clause was sufficient to determine that "Congress intended the MDA to preempt at least some state law").

As a result, the statutory claims pleaded here in Counts I and II – which are duplicative of the common law claims – are similarly preempted because they challenge the safety profile that was reviewed and approved under the PMA process by the FDA. *See, e.g., Mendes v.*

Medtronic, Inc., 18 F.3d 13, 19 (1st Cir. 1994) (implied warranty claim under M.G.L. § 2-314 against manufacturer of Class III device is preempted); *Talbott v. C.R. Bard Inc.*, 865 F. Supp. 37, 52 (D. Mass. 1994) (preempting a claim under M.G.L. Ch. 93A § 2(a), *et seq*. for unfair and deceptive trade practices because these claims have "the potential to impose state requirements in addition to, or different than, the FDA's requirements.").

In sum, it is a matter of public record that the FDA regulates Seprafilm as a Class III device and that Seprafilm was approved under the PMA process. All aspects of Seprafilm's design, manufacture, and labeling received specific FDA review and approval. Therefore, Counts I, II, III, IV, and VII of the complaint – each predicated on state statutory or common law claims challenging the device's safety – are preempted.

B. Count V for Negligence *Per Se* Fails to State a Claim.

Illinois recognizes the tort of "negligence *per se*." *Mueller by Math v. Community Consol. School Dist. 54*, 678 N.E.2d 660, 667; 222 Ill.Dec. 788, 795 (Ill. App. Ct. 1997) (*citing Ney v. Yellow Cab Co.*, 117 N.E.2d 74; 2 Ill.2d 74 (Ill. 1954)). Required elements include proof of a statute or regulation establishing a relevant standard of care, violation of the statutory standard, and a resulting injury that was causally connected to the breach. *Id.* Claims "premised on a violation of FDA regulations" are not subject to preemption if "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 128 S. Ct. at 1011.

Here, however, the plaintiff alleges that Genzyme violated standards of care defined by regulations applicable only to prescription drugs and certain biological products. (*See* C. ¶ 46 A-E, 21 C.F.R. §§ 201.56(a), (b) and (d); 201.57(e); 201.57(f)(1) and (2).) The regulations pleaded in the complaint are not at all applicable to Class III medical devices and simply cannot be substituted for the device-specific requirements imposed by the FDA with regard to Seprafilm.

See 21 C.F.R. § 201.57 ("The requirements in this section apply only to certain kinds of prescription drug products.").

The failure to plead a relevant statute or regulation is not a mere technicality. The only relevant standard of care for claims involving Class III devices are those requirements imposed by the FDA as part of the PMA process. *See Riegel*, 128 S.Ct. at 1007 ("Unlike general labeling duties, premarket approval is specific to individual devices."). Here, because there is no allegation that Genzyme breached a relevant statutory standard of care or that it failed to adhere to the PMA-mandated requirements regulating the device, the plaintiff is not entitled to relief and Count V for negligence *per se* should be dismissed. Allowing Count V to proceed would be in clear violation of the MDA's express preemption clause.

III. Count VI (Breach of Express Warranty) Fails Because It Does Not Identify The Purported Express Warranty.

In order to prevail on a breach of express warranty claim under Illinois law, the plaintiff must show "a breach of an affirmation of fact or promise that was made a part of the basis of the bargain." *Hasek v. DaimlerChrysler Corp.*, 745 N.E.2d 627, 634; 253 Ill.Dec. 504, 511 (Ill. App. 2001). "Since express warranties are contractual in nature, the language of the warranty itself is what controls and dictates the obligations and rights of the various parties." *Id. See also, e.g., Mitchell*, 126 F.3d at 915 n.9 (affirming dismissal of an express warranty claim as "entirely justified" because "without indication as to the substance of any express warranty," the plaintiff could not have prevailed).

Unless the complaint contains specific factual allegations about the nature of the express warranty, the claim will be dismissed. *See, e.g., Richman v. W.L. Gore & Assocs., Inc.*, 881 F. Supp. 895, 905 (S.D.N.Y. 1995) ("The complaint states only a conclusory legal claim with respect to the alleged breach of express warranty. Such a claim is not well-pleaded and cannot

withstand a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure . . . Inadequately pleaded factual allegations include those that are purely conclusory."); *Pulte Home Corp. v. Parex, Inc.*, 579 S.E.2d 188, 190-91 (Va. 2003) (merely parroting language that sets forth the legal bases for the creation of an express warranty is insufficient to state a claim for breach); *Gelormino v. J.C. Penney Co., Inc.*, 1997 WL 297601, *3 (Conn. Super. Ct. 1997) (striking express warranty claim from the complaint because "J.C. Penney has not alleged what, if any, express warranty existed" and concluding that allegation of a breach of an express warranty "not supported by any facts . . . is legally insufficient").

Here, plaintiff has failed to identify any specifics about the purported express warranty. There are no facts in the complaint about the nature or circumstances of any express warranty made by Genzyme to Mrs. Heisner. The conclusory allegations that Genzyme "expressly warranted" that Seprafilm was "safe, effective, fit and proper for its intended use" and that this warranty was false because Seprafilm "was not safe and was unfit for the uses for which it was intended," are insufficient to withstand a motion to dismiss. Therefore, Count VI should be dismissed.

IV. Aside From Preemption, Other Pleading Defects Doom the Complaint.

A. Every Count Fails Because the Defendant Had No Duty to Warn the Plaintiff.

The crux of this complaint is a series of failure to warn allegations, specifically, that the defendant failed to warn Mrs. Heisner about Seprafilm's allegedly "dangerous propensities." (*See, e.g.*, C. ¶¶ 20, 23-25, 39, 46, 50, 55). Under Illinois law, however, the defendant had no duty to warn the plaintiff.

Illinois, like virtually every State, follows the "learned intermediary doctrine," which requires manufacturers to direct warnings about prescription products, like Seprafilm, to the

medical community of physicians, and not to patients. *Kirk v. Michael Reese Hosp. and Medical Ctr.*, 513 N.E.2d 387, 392-93; 111 Ill.Dec. 944, 949-50 (Ill. 1987). As the Illinois Supreme Court has explained, "[t]he doctor, functioning as a learned intermediary between the prescription drug manufacturer and the patient, decides which available drug best fits the patient's needs and chooses which facts from the various warnings should be conveyed to the patient, and the extent of disclosure is a matter of medical judgment." *Id.* The doctrine applies equally to manufacturers of prescription medical devices. *See, e.g., Hansen v. Baxter Healthcare Corp.*, 723 N.E.2d 302, 311-12; 243 Ill.Dec. 270, 279-80 (Ill. App. Ct. 1999).

Here, every count in the complaint rests on a claim that the defendant failed to warn the *plaintiff* about some purported failing of Seprafilm. Because, as a matter of law, a failure to warn the plaintiff does not give rise to a cognizable claim, the motion to dismiss should be granted.

B. Every Count Fails Because of Formulaic Pleading of Conclusions Rather Than Facts.

Every count in the complaint resorts to pleading labels and conclusions, exactly the type of "formulaic recitation" that has been deemed unacceptable for a federal complaint. *See Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1964 (2007) ("While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level.") (internal citations, brackets omitted).

The negligence *per se* claim (Count V) exemplifies the problem. At best it states only a "formulaic recitation" and not a very good one. It lacks any facts about how, when or where

Genzyme failed to adhere to the requirements imposed on it by the FDA. What quality of the product was out of compliance? What specific aspect of the manufacture, label or marketing violated the federal standards? Answers to questions like these need to be pleaded in the first instance to pass *Bell Atlantic* muster.

Nor is it enough to specify the particular medical condition that supposedly resulted from the use of Seprafilm. As recognized by the PMA process itself, a Class III medical device by its very nature carries risks of adverse reactions, and the weighing of those risks and benefits is squarely within the province of the FDA, not state tort law. The specific allegations here, that Seprafilm caused Mrs. Heisner to develop "concrete intestines," do not provide enough factual grounds to sustain this lawsuit – especially since the plaintiff also alleges that the FDA is aware that Seprafilm may cause those very injuries. The main point of the PMA process is for the FDA to weigh the knowledge it has and determine the appropriate means of labeling for adverse reactions and other risks of use.

In short, every count uses the same formulaic approach to pleading: cookbook labels and conclusions that lack substance about the actual defect in design, manufacture, warning or marketing. The counts in the complaint are founded on no more than conclusory speculation and should be dismissed.

C. Count II (Violation of Massachusetts Consumer Protection Act) Should Not Proceed Because of Failure to Meet the Statutory Notice Requirement and Exemption.

In addition to the preemption defense, Count II should be dismissed because (1) the plaintiff fails to satisfy a prerequisite to suit and (2) the transaction is exempted. *First*, the plaintiff did not tender a demand letter at least thirty days before the filing of suit. *See* M.G.L. Ch. 93A § 9(3) ("At least thirty days prior to the filing of any such action, a written demand for relief, identifying the claimant and reasonably describing the unfair or deceptive act or practice

relied upon and the injury suffered, shall be mailed or delivered to any prospective respondent"). The notice requirement "is not merely a procedural nicety, but rather a prerequisite to suit," and failure to comply is fatal to the action. *Roberts v. Crowley*, 2008 WL 618929, *6 (D. Mass. March 6, 2008); *Rodi v. Southern New England School of Law*, 389 F.3d 5, 19 (1st Cir. 2004) (dismissing the claim under Fed. R. Civ. P. 12(b)(6) for failure to allege the required notification). Because the plaintiff has not alleged that he tendered the required written demand before filing this action, Count II cannot be salvaged.

Second, actions concerning the manufacture, marketing and labeling of Seprafilm are exempted from the Massachusetts consumer protection act because such actions are regulated and permitted by the FDA. Section 3 of the Massachusetts statute states: "Nothing in this chapter shall apply to transactions or actions otherwise permitted under laws as administered by any regulatory board or officer acting under statutory authority of the commonwealth or of the United States." Here, the precise actions about which the plaintiff complains – the marketing, labeling or manufacture of Seprafilm – are affirmatively regulated and permitted by the FDA, acting under authority of the Federal Food, Drug & Cosmetics Act. These activities fit squarely within the exemption provided in Section 3 of the Massachusetts statute. *Cf. Cabot Corp. v. Baddour*, 477 N.E.2d 399, 400-402 (Mass. 1985) (securities transactions are not within the scope of Chapter 93A because of the comprehensive federal and state regulatory scheme governing such transactions); *Darviris v. Petros*, 812 N.E.2d 1188, 1195-96 (Mass. 2004) (negligence by physician is not covered by Chapter 93A because "exhaustive statutory scheme" regulates medical malpractice claims); *Riccio v. Ford Motor Credit Co.*, 238 F.R.D. 44, 47-48 (D. Mass. 2006) (ruling on a 12(b)(6) motion that defendant's challenged conduct was not covered by Chapter 93A because the conduct was "governed, contemplated, and permitted by regulations").

Accord Talbott, 865 F. Supp. at 52 (deceptive trade practices claim under M.G.L. Chapter 93A against a medical device may not proceed).

Therefore, Count II of the complaint, seeking relief under the Massachusetts Consumer Protection Act, fails to state a claim and should be dismissed.

D. Plaintiff's Allegations Do Not Entitle Him to the Relief He Seeks Under the Wrongful Death or Survival Statutes.

In the circumstances here, where a person purportedly suffered injury from a product and then dies, only certain statutory relief is allowed. Here, the plaintiff has pleaded common law claims and common law relief without bringing the complaint within the proper boundaries of the Illinois Wrongful Death Act, 740 ILCS 180/1, and the Illinois survival statute, 755 ILCS 5/27-6. The principal defects include the following.

First, the complaint seeks damages that are not recoverable under the Wrongful Death Act, which allows compensation only for pecuniary injuries. 740 ILCS 180/2. In contradiction of the statute, the plaintiff here seeks punitive damages and other forms of relief that are not recognized by the Act.

Second, there is no meaningful reference to the Illinois survival act, only citations to the Wrongful Death Act. On that basis, any claims premised on a survival action for damages caused by injuries to Jayne Heisner while she was alive must be dismissed. The only "survival" statute referenced in the complaint is "740 ILCS 180/2" – a provision of the Wrongful Death Act.

Third, it is not at all clear that the proper party filed this action. An action under the Wrongful Death Act must be brought by the decedent's personal representative (i.e. executor or administrator). 740 ILCS 180/2. While the plaintiff alleges he is the "personal representative" of the decedent in paragraph 56 of the complaint, nothing else in the pleadings – including the

caption – indicates his status as either administrator or executor of the decedent's estate. The plaintiff is described merely as filing "individually and on behalf of Jayne Heisner," his deceased wife.

Therefore, the wrongful death and survival claims should be dismissed.

CONCLUSION

Wherefore, for the foregoing reasons, the court should grant this motion and dismiss all counts of the complaint.

Respectfully submitted,

Genzyme Corporation

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